REMARKS

1. **Status of the Claims**

As noted in the Office Action, claims 1, 7-9 12 and 14 are pending for examination on the merits. It is understood that the claims as examined by the Examiner are as the claims were set forth on pages 2 and 3 of Notice of Allowability issued on September 20, 2004 in the parent application. With that understanding, the claims have been amended as set forth above.

2. **Prior Art Rejection**

The claims have been rejected under 25 USC 102 (b) as being anticipated by Ragnhammar et al. (Int. J. Cancer 1993; 53:751-758). This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

As previously described, the present invention is directed to the finding that so called "active" immunotherapy treatment of a patient with an antibody directed against the cellular membrane antigen Ep-CAM induces an immune response by the patient's own body against carcinoma cells. Exhibit 1 attached to Applicants' response of October 31, 2003 describes clinical trials with administration of Applicants' product IGN 101 together with a vaccine adjuvant, wherein the first section on page 2 of the brochure explains and schematically illustrates the biological response of administration of IGN 100 to induce production by the patient of antibodies that destroy Ep-CAM positive tumor cells.

The Examiner has rejected the present claims over Ragnhammar, urging that the reference describes "a monoclonal murine antibody termed 17-1A in a dosage range of 0.01-4 mg (specifically, it is taught that the dose is 1.0 mg – see page 751)". But contrary to the Examiner's assertion, Ragnhammar does not truly teach each and every one of the limitations of the present claims as would be required for a proper rejection under 35 USC 102.

Claim 1 is directed to a composition comprising an antibody directed against the cellular membrane antigen Ep-CAM, together with at least one adjuvant useful in the formulation of vaccine to thereby enhance an immune response. This type of composition provides for an active immunotherapy of cancer patients, and permits the use of a low dosage amount of the antibody, as set forth, for example, in claim 7.

Ragnhammar at page 751, the right hand column, line 4 under "treatment schedule", describes the intravenous administration of a high amount of antibodies, specifically 400 mg of MAb 17-1A. But this disclosure in Ragnhammar does not teach a combination of such an antibody with an adjuvant useful in the formation of a vaccine to thereby enhance an immune response (as defined in Applicants' claim 1), nor does this portion of Ragnhammar describe low dosage amounts of the antibody as recited, for example, in claims 7, 12, 14, and 17-25.

The Examiner additionally refers to the disclosure in Ragnhammar at page 751, right hand column, the third sentence of the second paragraph under the heading "treatment schedule", wherein the reference describes the intradermal injection of "MAb 17-1A (1.0 mg)". But a

proper reading of the reference makes it clear that this portion of Ragnhammar is not actually teaching the present invention. Rather, this portion of Ragnhammar suggests that concern about allergic reactions to MAb 17-1A can be tested by means of immediate allergic reaction (ITAR) by administering intradermally a dose of 1.0 mg of the antibody. But this teaching does not describe a combination of the antibody with an adjuvant useful in the formation of a vaccine to thereby enhance an immune response (Applicants' claim 1), nor does it describe an individual dosage vaccine formulation comprising 0.01-4 mg of the antibody (Applicants' claim 17), nor does it describe a method of treating cancer disease according to Applicants' method claims, since this portion of the reference relates merely to allergic response testing and not therapeutic treatment.

In summary, Ragnhammar is directed to treatment of cancer with high dosage amounts of MAb 17-1A, specifically by means of 400 mg or more of the antibody. This is far different than the present invention which is directed to active immunotherapy of cancer patients with low amounts of an antibody directed against the cellular membrane antigen Ep-CAM. The only disclosure in Ragnhammar relating to smaller amounts of the antibody concerns testing for allergic reactions, and not for actual cancer treatment in a patient.

In view of the above, Applicants submit that Ragnhammar does not teach the claimed invention and that the rejection under 35 USC 102 should be withdrawn.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____
Leonard R. Svensson, #30,330

P.O. Box 747
Falls Church, VA 22040-0747
(714) 708-8555

LRS/lmt
5012-0104PUS1

Attachment(s)

Certificate of Transmission
I hereby Certify that this correspondence is being facsimile transmitted to the Patent and Trademark Office:
On June 22 2005
Date
Signature
Loni M. Tillman
Typed or printed name of person signing certificate